

## **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 21-48 are in the case.

### **I. THE OBVIOUSNESS REJECTION**

Claims 1, 3, 12-15 and 17-20 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 5,520,166 to Ritson in view of U.S. Patent 3,521,643 to Toth. That rejection is respectfully traversed.

As now claimed, the invention is directed to an actuator for an inhaler for delivering medicament by inhalation. The actuator comprises a main body comprising a tubular member for receiving a canister containing medicament and having a valve stem extending therefrom; and an outlet assembly, as a part formed separately of the main body, comprising a mouthpiece for guiding medicament to the mouth of a user and a nozzle block for receiving the valve stem of the canister and delivering medicament from the canister into the mouthpiece. At least a part of the outlet assembly is configured so as to deform and optionally break on withdrawal of the outlet assembly from the main body so as to prevent re-use of the outlet assembly.

Ritson describes a medication cassette for an automatic aerosol medication delivery system. At column 8, line 60-63, Ritson discloses that the cassette components (i.e., housing, mouthpiece and canister) "cannot be non-destructively disassembled so that the cassette cannot be subsequently operatively reassembled and used." However, Ritson does not describe how and what should break during disassembly. Referring to the embodiment disclosed in Figs. 4 and 5, disassembly of the housing and the mouthpiece would likely result in deformation of the tabs 42 on the

housing and/or the corresponding apertures 28 on the mouthpiece, thereby only affecting the means for connecting the two components, and leaving the functional parts, such as the nozzle block 21 and its support structure 29, unaffected. In that event, the Ritson mouth piece would still be functional and could be reused to actuate a canister in a simple manner, with or without the housing.

New claim 21 presented herewith specifies that the outlet assembly (which directly corresponds to the mouth piece according to Ritson) is configured so as to deform and optionally break "so as to prevent reuse of the outlet assembly". In the embodiment of the outlet assembly discussed in the specification, the nozzle block is supported by two upper and two lower connections between the mouth piece and the nozzle block, of which the two lower ones are configured to deform or optionally break upon withdrawal of the outlet assembly. By this, the outlet assembly is permanently deformed so that the nozzle block is no longer aligned with the valve stem, and lacks support from the deformed or broken connections. The outlet assembly is therefore disabled, and cannot be used to again actuate a canister.

The above-noted deficiencies of Ritson are not cured by Toth. Toth is relied upon by the Examiner for an alleged disclosure of a device having a body and a mouthpiece made of material of different constitution. Toth otherwise is irrelevant to the presently claimed invention. One of ordinary skill would not have been motivated to combine the disclosures of Ritson and Toth and, even if such a combination had been attempted (it is believed that would not have occurred to one of ordinary skill), the presently claimed invention would not have resulted or have been rendered obvious thereby. Absent any such motivation, a *prima facie* case of obviousness does not exist

in this case. Reconsideration and withdrawal of the outstanding obviousness rejection are accordingly respectfully requested.

## **II. ALLOWABLE SUBJECT MATTER**

It is noted, with appreciation, that claims 2, 4-7 and 16 are allowable. For the reasons discussed above, it is believed that the new claims presented with this response are in allowable condition. Early notice to that effect is respectfully requested.

## **III. SPECIFICATION**

The specification has been amended to include customary headings, including a brief description of the drawings. In addition, a new abstract is presented based on new claim 21. No new matter is entered.

## **IV. PRIORITY**

A certified copy of the Swedish priority patent application for this case was filed during the international phase of the underlying PCT International Application No. PCT/SE9802038. A copy of that priority document should be in the USPTO file for the present application, having been forwarded by WIPO to the U.S. Designated Office. Acknowledgment of receipt of the priority document is requested in the next paper to issue in this case.

**V. AMENDMENTS**

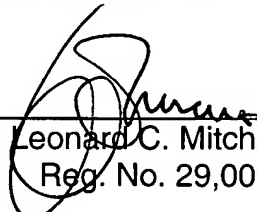
New claims 21-48 are presented for consideration. The claims are supported by the originally filed application and no new matter is entered. Entry and favorable consideration are respectfully requested.

Allowance of the application is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_

  
Leonard C. Mitchard  
Reg. No. 29,009

LCM:lfm  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100